

## Brief Reports

### Enhancing Medication Compliance for People with Serious Mental Illness

Medication compliance is an important factor in treatment outcomes for all medical and psychiatric disorders (Cramer and Spilker, 1991). Unfortunately, no population can be assumed to be excellent compliers with prescribed regimens (Cramer et al., 1989). Although a number of investigators have established that poor compliance is a problem in psychiatric disorders (Hogan et al., 1983; Weiden et al., 1994), effective interventions to enhance compliance have yet to be evaluated. We previously surveyed the literature to assess the extent of compliance with medications for schizophrenia and mood disorders in comparison to physical disorders (Cramer and Rosenheck, 1998). Overall compliance rates were 58% for antipsychotic medication, 65% for antidepressant medications, and 76% among medications for physical disorders. However, the apparent differences might have been attributable to the methods used to estimate compliance.

We developed the Medication Usage Skills for Effectiveness (MUSE) program to teach severely mentally ill patients simple techniques to remember daily medication doses. This study was designed as a prospective, randomized clinical trial of the effect of MUSE on medication compliance and health outcomes among a diagnostically heterogeneous sample of psychotic and nonpsychotic patients participating in an acute care day program.

#### Methods

The study was conducted within the Veterans in Crisis day program at the VA Connecticut Healthcare System. The program treats patients who are in crisis and require stabilization to avert hospitalization or who need intensive support after discharge. Patients with an axis I clinical diagnosis were invited to participate in MUSE if: a) they lived in an unsupervised setting, b) were prescribed an oral psychotropic medication, c) were responsible for taking medications without assistance, and d) were willing to use a special bottle for the medication. If multiple psychotropic medications were used, the one with the highest number of daily doses (e.g., TID as contrasted with BID) was selected for monitoring. Symptom severity was assessed with the Brief Symptom Inventory© (NCS Assessments, Minneapolis, MN; Derogatis and Derogatis, 1996). After complete description of the study to the patients, written informed consent was obtained.

Randomization was made to either the intervention group (special instruction and other reinforcing techniques) or the control group (standard care). Follow-up assessments were completed monthly for 6 months. All patients were asked to use microelectronic devices (MEMS©; APREX, division of APRIA Inc.) to monitor compliance. MEMS units are special caps that attach to standard medication vials that record the date and time of each bottle opening. Data can be down-

loaded to a computer using proprietary software to display dosing patterns as calendar plots, lists of dose times, or dose intervals. The intervention group used caps with digital displays showing the number of times the bottle had been opened that day, and number of hours since the previous opening; the control group used caps without digital displays. Patients were instructed to use only the special bottle and cap for the medication and to remove only one dose at a time.

The intervention group received instruction on life skill techniques from a lay research assistant. At the initial session (approximately 15 minutes), patients were taught how to develop cues to remember dose times. They were asked to define a cue that would fit into their lifestyle, such as a specific clock time, mealtime, or another daily ritual (e.g., shaving or other bathroom activity, watching the evening news, etc). Patients were also instructed to regularly check the display of data on the cap to see when the next dose was due. During monthly follow-up visits, intervention patients were given visual feedback by displaying a calendar on the computer monitor. The calendar listed the number of bottle openings (presumptive doses) each day. The patients and research coordinator discussed the pattern, noting days with zeros or fewer openings than prescribed. Sessions lasted less than 5 minutes. The control group received several minutes of general instructions about the importance of taking their medications.

Compliance rates were calculated as proportion of days during which the number of bottle openings matched the prescribed number of doses (Cramer et al., 1989). Compliance data are reported for the first month when only cues and cap displays were provided ( $N = 60$ ), and the entire 6-month period ( $N = 45$ ) during which calendar feedback was also provided, starting at month 1. Comparisons between groups are made by one-tailed Student's *t*-test for continuous data (compliance rates).

#### Results

Sample characteristics are presented in Table 1. Data are available for 60 patients through month 1, and for 45 patients through month 6. Preliminary data demonstrate significant differences in compliance between patients in the intervention and control groups. Mean 1-month compliance rates were  $81 \pm 22\%$  ( $N = 31$ ) for the intervention and  $68 \pm 27\%$  for the control group ( $N = 29$ ;  $t = 2.04$ ,  $df = 58$ ,  $p = .023$ ) before the first visual calendar feedback session. Of those patients who completed the trial, mean duration of participation was  $142 \pm 80$  days for the intervention group and  $142 \pm 54$  days for the control group. Mean overall compliance for the intervention group ( $N = 25$ ) was  $76 \pm 22\%$ , compared with  $57 \pm 30\%$  for the control group ( $N = 20$ ) patients ( $t = 2.52$ ,  $df = 43$ ,  $p = .008$ ). Table 2 shows a typical calendar display of dosing data.

TABLE 1  
*Demographic Characteristics at Baseline*

	Intervention	Control	
No. of patients randomized <sup>a</sup>	41	40	
Gender (% male)	85%	88%	
Age (mean yr)	46 ± 9	48 ± 10	<i>df</i> 85, <i>t</i> = -.64 (NS)
Clinical diagnosis			
Schizophrenia, schizoaffective	12	14	
Depression, bipolar	14	10	
PTSD (± depression)	5	5	
No. of medications			
Psychotropic	2.8	2.7	<i>df</i> 86, <i>t</i> = .51 (NS)
Medical	1.2	1.4	<i>df</i> 86, <i>t</i> = -.69 (NS)
All	4.0	4.1	<i>df</i> 86, <i>t</i> = -.18 (NS)
Brief Symptom Inventory score	.78 ± .45	.69 ± .38	<i>df</i> 79, <i>t</i> = .99 (NS)

<sup>a</sup>Living situation varied over 6 months for this population in transition.

TABLE 2  
*Example of a Patient Dosing Calendar*

MON	TUE	WED	THU	FRI	SAT	SUN
2	2	2	2	2	2	2
2	0	2	2	2	0	0
0	2	2	2	2	2	2
2	2	2	2	2	0	0
0	0	0	0	0	0	0
1	2	2	2	2	2	2
2	2	2	2	2	1	1
1	2	2	2	2	2	2

Zero doses taken on 23% of days; One dose taken on 7% of days; Two doses taken on 70% of days.

## Discussion

These data demonstrate the potential effectiveness of a simple intervention program with concrete cues to improve the capacity of patients with a variety of psychiatric disorders to take medications regularly. The combined use of personalized cues, visual reminders (digital display) on the caps, and visual calendar feedback at follow-up visits appear to be effective in improving medication compliance among psychiatric patients in crisis.

The preliminary groups are too small to conduct analyses by diagnostic subgroups at this time. We continue to enroll patients to provide data for analyses of differences between patients with psychotic and nonpsychotic disorders and the eventual relationship of compliance to health service utilization, clinical outcomes, and other factors (disease severity, attitude toward medication, alliance with providers). The sample heterogeneity is appropriate because these techniques will be used in the general psychiatric population. Failure to return for follow-up visits is not necessarily attributable to medication noncompliance. Many patients had structural reasons, such as hospitalization, moved residence, and lack of transportation.

Severely mentally ill patients who are in crisis are at a point where following prescribed regimens is particularly important in optimizing the effectiveness of pharmacotherapy, thereby preventing decompensation and rehospitalization. Many factors related to the disease severity (e.g., cognitive

disorganization and poor memory) could contribute to an inability to self-medicate. Compliance therapy is a practical approach to therapy, albeit by self-report as demonstrated by Kemp et al. (1996). The concrete cues and supportive counseling used in this study reduce these problems by anchoring patients' ability to establish daily routines that foster medication compliance. Although we based compliance rates on observation of a single medication, previous research with monitors for multiple medications has shown that when a patient remembers a dose time, all medications are taken almost simultaneously. When a dose time is forgotten, all medications are missed (Cramer et al., 1990b). These preliminary data also suggest a decline in compliance over time, as previously noted in other populations (Cramer et al., 1990a). This study suggests that the techniques used to teach patients medication usage skills are effective, particularly when they are designed to avoid issues of power or control (Demyttenaere, 1997) between patients and providers by focusing on the development of adaptive, individualized skills (Fenton et al., 1997).

## Conclusion

These preliminary data demonstrate the potential applicability of a simple, focused intervention technique to enhance medication-taking behavior.

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## Dimensions of Social Adjustment in Schizophrenia: A Factor Analysis

Newer and more effective treatments for schizophrenia are forcing greater attention to the definition of treatment outcome. Investigators are challenged to document the impact of drug and psychosocial treatments on a range of characteristics including social and occupational functioning, subjective quality of life, family burden, and cost (Attkisson et al., 1992; Meltzer et al., 1993). An obvious question involves whether and how outcome in one area is related to outcome in another area. Brekke (1992) reported a factor analysis using different measures of social adjustment in a cohort of individuals with schizophrenia, and found that instrumental, social, and illness domains of adjustment were relatively independent. Although this finding is consistent with notions originally put forth by Strauss and Carpenter (1977; Carpenter and Strauss, 1991), it is the only recent report examining the interrelationships between different outcome measures in this population.

Our group is conducting a study of recovery processes in schizophrenia, which involves longitudinal assessments of symptoms, neurocognition, and social adjustment beginning with the stabilization of a psychotic exacerbation. The study population is chronic, with frequent relapses and many years of impaired functioning. We were faced with the question of defining the most important aspects of "social adjustment" for this population, and made an a priori decision to look at three domains: treatment compliance; basic social behaviors (communication skills, the ability to maintain friendships);

and subjective quality of life. We could not, however, agree on a hypothesis regarding how functioning in these three domains might be related. Following Brekke's (1992) strategy, we here report a factor analysis of outcome variables from this study.

## Methods

Subjects completed assessment batteries at 3-month intervals for up to 2 years immediately after inpatient treatment for an acute exacerbation. The data reported herein are from initial assessments of the first 46 individuals recruited into the project. Subjects were recruited upon admission to an outpatient continuing day treatment program, and all had been hospitalized for treatment of an acute symptom exacerbation within the 30-day period before recruitment. Written, informed consent was obtained for all subjects after the procedures were fully explained; no one under the age of 18 was included in the study. All subjects were interviewed with the Structured Clinical Interview for DSM-IV to establish axis I diagnoses. Twenty-six (57%) of the subjects received a diagnosis of schizophrenia, and 20 (43%) were diagnosed with schizoaffective disorder. Twenty-nine (63%) were male, and 94% were Caucasian. The mean age was 39 years (SD = 12 years), the mean age of illness onset was 18 years (SD = 7.9 years), and subjects had an average of 7.7 prior hospitalizations (SD = 3.5).

A factor analysis was conducted using data from instruments assessing social adjustment in the three dimensions identified a priori: treatment compliance, social behavior, and quality of life. Treatment compliance was measured using 100-point visual analog scales, with a score of 0 signifying no compliance and 100 meaning perfect compliance. Each subject received two ratings, one each for compliance with medication and with nonmedication treatments.

Social behavior and quality of life ratings were obtained with the Social Behavior Scale (SBS; Wykes and Sturt, 1986) and the Quality of Life Interview (Lehman, 1988). The SBS assesses behavioral capacities felt to determine overall adjustment in individuals with chronic schizophrenia. We were interested in the communication skills subscale, which documents subjects' abilities to initiate and maintain conversations. The Quality of Life Interview (QOLI) was developed by Lehman to assess individuals' objective performance and subjective satisfaction with their circumstances, resources, and interpersonal relations. We included the QOLI objective score for social relations, which documents subjects' abilities to form and maintain social relations. We also included 3 QOLI subjective scores: general life satisfaction, and satisfaction with social relations and daily activities.

Treatment coordinators assessed subjects' treatment compliance during the 2-week period immediately after discharge from the inpatient unit. As a validity test, a subsample of this cohort was also rated for compliance with a 4-point Likert scale developed and validated by McEvoy et al. (1989). The Pearson correlation coefficient for ratings on this instrument and the two visual analog scales were .86 and .90. Trained research interviewers made SBS and QOLI ratings; the interrater reliability coefficient for the three items included in the SBS communication skills subscale were .84,